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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,953	02/13/2001	R. Sanders Williams	UTSD:674US/SLH	2337

7590 08/09/2005

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EXAMINER
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LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/782,953

Applicant(s)

WILLIAMS ET AL.

Examiner

Samuel W. Liu

Art Unit

1653

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 22 July 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☒ The Notice of Appeal was filed on 22 July 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: none.  
Claim(s) objected to: none.  
Claim(s) rejected: 59,61,62 and 70.  
Claim(s) withdrawn from consideration: none.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

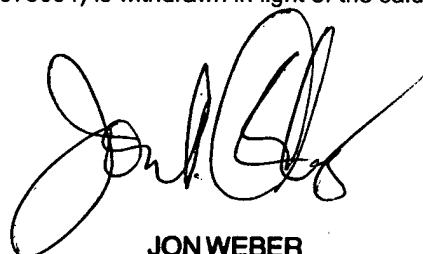
11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☒ Other: See Continuation Sheet.

Continuation of 11. does NOT place the application in condition for allowance because:

The claim rejections under 35 USC 103(a) by Chin et al. and Sussman et al. mailed 4/20/05, stands for the same reasons set forth in the Office action. Applicants argue that the Chin et al. and Sussman et al. references improperly rely on inherency (i.e., modulating MCIP [i.e., myocyte-enriched calcineurin-interacting protein] is performed through regulating calcineurin), and that the inherency is not necessarily known, and thus, obviousness cannot be predicted on what is unknown (pages 6-7).

The applicants' argument is found to be not persuasive because when administration of the calcineurin inhibitor, cyclosporine, to the subject inevitably leads to regulating (up- or down) the muscle cell growth, and because the claimed method is directed to regulating muscle cell growth but not the MCIP's expression itself which is considered to be a molecular mechanistic step of the regulation. The process taught by the references comprises the same steps set forth in the instant claims. Therefore, it is not required for one skilled in the art to know the said mechanism prior to the administration thereof in order to regulate muscle cell growth since the claimed method comprises the steps (a) –(c) but is not directed to the mechanism thereof, i.e., regardless of the mechanism. As stated in the Office action (page 8), calcineurin is an activator for induction of MCIP1 expression, and cyclosporin is an inhibitor (i.e., antagonist) of the calcineurin for muscle growth. Thus, the administration of the cyclosporin would negatively regulate the muscle cell growth (regulation of the muscle cell growth is the subject matter of the current invention); and therefore, Chin et al. and Sussman et al. references are qualified as the obviousness art against the current application.

Continuation of 13. Other: Note that the declaration of Beverly Williams and R. Sanders Williams under 37 C.F.R. 1.131 filed 7-22-05 has been considered. The rejection under 35 USC 102(e) by Edge A. (UA Pat. No. 6673604) is withdrawn in light of the said 1.131 declaration.



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**